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| APPLICATION NUMBER | FILING OR 371 (c) DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|------------------------|-----------------------|------------------------|
| 10/716,577 | 11/18/2003 | Kathryn E. Uhrich | 03195609 |

26565
MAYER, BROWN, ROWE & MAW LLP
190 SOUTH LASALLE ST
CHICAGO, IL 60603-3441

CONFIRMATION NO. 6252

FORMALITIES LETTER



OC000000013117964

Date Mailed: 06/30/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

02/03/2005 BABRAHA1 00000123 10716577

01 FC:1051

130.00 OP

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. The specification, claims, or abstract page(s) submitted is not acceptable and cannot be scanned or properly stored because:
 - Papers must be legibly written either by a typewriter or mechanical printer in permanent ink or its equivalent in portrait orientation on flexible, strong, smooth, non-shiny, durable, and white paper. Application papers must be presented in a form having sufficient clarity and contrast between the paper and the writing thereon to permit the direct reproduction of readily legible copies in any number by use of photographic, electrostatic, photo-offset, and microfilming processes and electronic reproduction by use of digital imaging and optical character recognition. Pages 1-115 are not in compliance with 37 CFR 1.52(a).
- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121 are required. The drawings submitted are not acceptable because:

- The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 1-3, 17, 37-39.
- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

For questions regarding compliance to these requirements, please contact:

- **For Rules Interpretation, call (703) 308-4216**
- **To Purchase PatentIn Software, call (703) 306-2600**
- **For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov**

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$130** for a Large Entity

- **\$130** Late oath or declaration Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

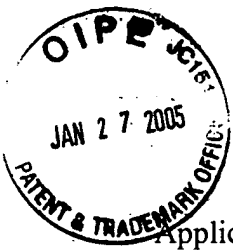
A copy of this notice MUST be returned with the reply.



Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/716,577

Applicant: GIROUX

Filed: November 18, 2003

Title: IMMEDIATE-RELEASE FORMULATIONS OF ACID-LABILE PHARMACEUTICAL COMPOSITIONS

Art Unit: 1615

Examiner: Unknown

Docket No.: 03195609

Customer No.: 26565

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY
"EXPRESS MAIL"
"Express Mail" mailing label number
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Date of Deposit: January 27, 2005
I hereby certify that this paper or fee is being
deposited with the United States Postal Service
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CFR 1.10 on the date indicated above and is
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Tim Hubalk

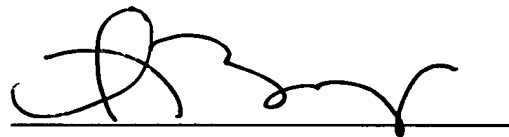
TRANSMITTAL LETTER

Dear Sir:

Enclosed herewith are the following for the above-captioned application:

1. Response to Notice of Missing Parts of Nonprovisional Application;
2. Executed Declaration and Power of Attorney;
3. Check in the amount of \$2,290.00;
4. Supplemental Application Data Sheet; and
5. Return postcard.

Respectfully submitted,



Amanda T. Barry
Reg. No. 51,435

Date: January 27, 2005

MAYER, BROWN, ROWE & MAW LLP
P.O. Box 2828
Chicago, Illinois 60690-2828
Telephone: (312) 701-7283
Facsimile: (312) 706-9000



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/716,577

Applicant: GIROUX

Filed: November 18, 2003

Title: IMMEDIATE-RELEASE FORMULATIONS OF ACID-LABILE PHARMACEUTICAL COMPOSITIONS

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Alexandria, VA 22313-1450

RESPONSE TO NOTICE TO FILE MISSING PARTS
OF NONPROVISIONAL APPLICATION

Dear Sir:

1. ☒ This replies to the Notice to File Missing Parts of Nonprovisional Application mailed June 30, 2004. A copy of the Notice to File Missing Parts of Nonprovisional Application is enclosed.
2. ☒ The Oath or Declaration was missing. A copy of the Combined Declaration and Power of Attorney is being submitted under 37 CFR 1.51(b)(2) and 1.53(f).
3. ☒ This filing is by a ☒ large entity.
☐ small entity,
☐ which was declared at the time of filing the application.
☐ which is being declared now, and a separate refund request for the application fee accompanies this paper.

4. Completion Fees

- a. The surcharge for filing the required oath/declaration is \$130.00 for large entity.

02/03/2005 BABRAHA1 00000123 10716577

02 FC:1255

2160.00 OP

5. Extension of Time

- ☒ Applicant petitions for an extension of time for five months, including payment of the appropriate fee in the amount of \$2,160.00. If an additional extension of time is required, please consider this a petition therefore.
- ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

6. Total Fees Due

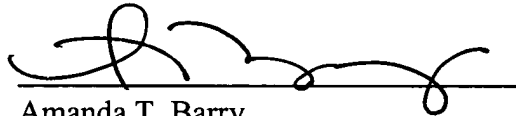
| | |
|------------------|------------|
| Completion Fees: | \$130.00 |
| Extension Fees: | \$2,160.00 |

TOTAL FEE DUE: \$2,290.00

7. Payment of Fees

- ☒ Attached is a check in the amount of \$2,290.00
- ☐ Authorization is hereby made to charge the amount of _____ to Deposit Account No. 13-0019
- ☒ Charge any additional fees required by this paper or credit any overpayment to Deposit Account No. 13-0019. A duplicate paper is attached for this purpose.

Respectfully submitted,


Amanda T. Barry
Reg. No. 51,435

Date: January 27, 2005

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Chicago, Illinois 60690-2828
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